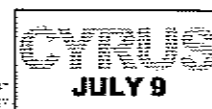


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Biotech Company Fires Chief and Others Over Handling of Data

By ANDREW POLLACK

A biotechnology company developing what was expected to be a groundbreaking blood test for Down syndrome fired its chief executive, a top research official and three other employees Monday after an investigation into "mishandling" of test data and results.

The company, Sequenom, announced the mishandling of the data in April, saying that the superlative results it had announced for its prototype test could no longer be trusted. A committee of independent board members then hired a law firm to conduct an investigation.

Sequenom said Tuesday that its investigation concluded that the company had "failed to put in place adequate protocols and controls" for studies and that some employees had failed to exercise adequate supervision. As a result, the company said in a regulatory filing Monday, "inadequately substantiated claims, inconsistencies and errors" about the Down syndrome test had been disclosed to investors.

The board fired Harry Stylli, the chief executive, and Elizabeth Dragon, the senior vice president of research and development, effective immediately, as well as three other employees whose names were not disclosed. Paul Hawran, the chief financial officer, and Steven Owings, the vice president for commercial development of prenatal diagnostic tests, resigned.

The company said the individuals who were dismissed or resigned had denied any wrongdoing. But it said the "committee's investigation has raised serious concerns, resulting in a loss of confidence by the independent members of our board of directors in the personnel involved."

Sequenom's announcement left many questions unanswered, in particular how exactly the data was "mishandled" and whether what happened was mere sloppiness or outright falsification and fraud.

The lack of detail prompted one investor on Sequenom's conference call Monday to accuse the company of "dancing around" what had happened, saying that would undermine investor confidence in the company.

Harry F. Hixson Jr., the chairman of the company, replied that the company could not say more because it was under investigation by the Securities and Exchange Commission and had been sued by shareholders. Sequenom said it would present the results of its investigation to the staff of the S.E.C.

Still, Mr. Hixson said that it did not appear that the officers who were fired or quit had profited financially "from any of the transactions here."

Sequenom, based in San Diego, was developing a test to detect the chromosomal abnormality Down

syndrome in fetuses, using a sample of the pregnant mother's blood. Such a noninvasive test might have eventually replaced the tests now used, amniocentesis and chorionic villus sampling, which are more invasive and can cause miscarriages.

The company's work drew widespread attention from Wall Street, the medical community and the news media, especially after it was reported that in early trial runs the test was virtually perfect in detecting Down syndrome, with no false positives or false negatives. Down syndrome, in which a person has an extra copy of a particular chromosome, is marked by some mental retardation and unusual facial characteristics.

The data, though announced by the company, had not been published in peer-reviewed medical journals.

The company's shares, which had been as high as \$28 a year ago, fell sharply in late April when the company said the data could no longer be trusted. In after-hours trading Monday, the stock fell by nearly half to \$3.23.

Mr. Hixson, a former chief operating officer at the biotechnology giant Amgen, was named as the company's interim chief executive. The company said it was taking numerous steps to correct the problems, such as a new organizational structure, new training for employees and new procedures for storing samples.

Mr. Hixson said that the company still had confidence in its technology. "We continue to believe that Sequenom has the potential to develop important noninvasive prenatal diagnostic tests," he said, adding that the data problems were "more a setback in time than anything else."

He did not say, however, when the Down syndrome test, which the company had initially expected to introduce last June, might be ready. The company has said that data on the test's performance will have to be validated by independent researchers.

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